

REMARKS

The Office Action dated October 31, 2005 has been thoroughly reviewed. Claims 58-60, 69-101 and 104-113 are currently pending. Claims 58, 100, 101, 104 and 113 are independent. Claims 61-68, 102 and 103 have been canceled without prejudice and/or disclaimer of subject matter. Claims 104-113 have been added to afford Applicant a more complete scope of protection that Applicant deems herself entitled to. No new matter has been added. Claims 58, 60, 86-88, 100 and 101 have been amended. The issues raised in the outstanding Office Action are addressed below.

Interview

Applicant wishes to thank the Examiner for the time and courtesies extended to Applicant, Amie Franklin (an Officer of Oxyband Technologies, Inc., the assignee of the subject application) and Applicant's below signed representative. Applicant is of the opinion that much was accomplished during the interview, in that Applicant gained a better appreciation of the Examiner's concerns, and the Examiner acquired a better understanding of Applicant's invention.

Objection To The Title

The title of the application was objected to on page 2 of the Action for being non-descriptive. While not arguing the merits of the Examiner's position, Applicant has provided a new title along the lines of that which was suggested by the Examiner, which Applicant feels more closely corresponds to the claimed invention. Accordingly, Applicant now respectfully requests that this objection be withdrawn.

Prior Art Claim Rejections

Claims 58-59, 62, 63, 66-68, 70-71, 74, 78-80, 86, 93, 96, 97, 99 and 102-103 were rejected under 35 U.S.C. §102 as reciting subject matter allegedly disclosed in U.S. patent no. 5,792,090 (Ladin), for the reasons set out on pages 2-4 of the Action. The remainder of the claims were rejected variously under 35 U.S.C. §103 over Ladin in view of a number of other prior art references, as set out on pages 4-10 of the Action. For the following reasons, the claimed invention is patentable over the prior art.

The Invention

Claim 104 is directed to a tissue dressing apparatus for supplying one or more predetermined gases to a target area. The apparatus includes a top layer having gas barrier properties, a bottom layer having gas transfer properties, a reservoir formed from the top and bottom layers being sealed together and a preset volume of one or more predetermined gases at concentrations greater than atmospheric included within the reservoir. The tissue dressing apparatus is non-gas generating. Claims 58, 100, 101 and 113 recite similar patentable features.

It is a particular feature of the claimed invention that the tissue dressing apparatus does not generate gas(es). Since the apparatus is non-gas generating, the reservoir of the apparatus contains the one or more predetermined gases for application to a target area prior to use at concentrations greater than atmospheric. Thus, for example, when the predetermined gas is oxygen, the oxygen level contained in the reservoir is preset at a concentration greater than atmospheric so that the tissue adjacent to the bottom layer is exposed to the oxygen to improve healing (for example). The prior art cannot achieve this without having to generate the oxygen by chemical reactions, electrochemical reactions or via a tethered external source.

The Cited Prior Art

U.S. Patent no. 5,792,090 to Ladin

As understood by Applicant, Ladin discloses an oxygen generating wound dressing. The device includes a solid substance catalyst (potassium permanganate) which is used to react chemically with hydrogen peroxide to release oxygen gas. As shown in Fig. 1 of Ladin, a two layer hydrogel comprises the oxygen supply – one layer containing oxygen generating catalyst and the other an absorbent for absorbing the solution for providing the oxygen – i.e., (a liquid) hydrogen peroxide. In use, one would open the top of the device (cap 203), and pour a hydrogen peroxide solution therein, where it would be absorbed by the absorbent and then react with the catalyst to form oxygen and water (a liquid). The generated oxygen passes through an oxygen permeable membrane where it then may permeate the wound (column 8, lines 18-54; Figs. 1, 2a and 2b).

U.S. Patent no. 5,008,110 to Benecke

As also understood by Applicant, Benecke is directed to a transdermal drug patch device for administering an active pharmaceutical to a patient. The device includes a drug reservoir that contains the drug formulation. The drug reservoir is sandwiched between an upper and a lower solvent barrier film that are made from a material such as a polyester that will not absorb the drug and/or skin permeating enhancing solvent which dissolves. The drug reservoir and solvent barrier films are encapsulated within a hermetically-sealed compartment that protects the drug formulation from common environmental factors such as water vapor, oxygen, and light which can adversely affect the stability and efficacy of the drug formulation.

U.S. Patent no. 6,565,936 to Peiffer

This patent is understood to be directed to a film laminate consisting of biaxially oriented polyester film and another film laminated onto the polyester film. The polyester film comprises a base layer at least 80% by weight of which is composed of a thermoplastic polyester, at least one cover layer and a metallic or ceramic layer located on the cover layer.

U.S. Patent no. 6,465,709 to Sun et al.

Sun et al. is understood by Applicant to be directed to a multi-layer exothermic bandage having an oxygen-impermeable layer, a water-impermeable layer, a heating element layer comprising an oxidizable material, and an active agent layer. The device is used to administer active agents through a barrier membrane (e.g., skin) with the aid of heat.

U.S. Patent no. 6,000,403 to Cantwell

Cantwell is understood to disclose a topical hyperbaric bandage having a gas diffusion resistant flexible and/or resilient sheet material and including an adhesive layer adapted to be affixed to the skin. The adhesive layer is adapted to surround a treatment area, at least one release layer disposed over the adhesive layer and a device that supplies a therapeutic gas to the treatment area.

U.S. Patent no. 4,764,382 to Kydonieus

Kydonieus is understood by Applicant to be directed to a device for the controlled release and delivery of a pharmacologically active agent. The device consists of a vinyl gel layer and a pharmacologically active agent uniformly dispersed in the layer in a pharmacologically effective amount.

Analysis

Anticipation/Novelty

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP §2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See also MPEP § 2131.02, "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Obviousness

To establish a prima facie case of obviousness, three basic criteria must be met:

- there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- there must be a reasonable expectation of success; and
- the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP § 2143.

Findings

Applicant respectfully submits that the Action has, with regard to anticipation, failed to offer any evidence that the cited Ladin reference discloses each and every feature recited in

the claims and, with regard to obviousness, has failed to offer any evidence that any of the cited prior art would have taught or suggested to one of skill in the art, the claimed invention. Specifically, Applicant could not find any express or inherent information, in any of the cited references, either alone or in combination, which would either disclose, teach or suggest to one of skill in the art at the time the invention was made of a non-gas generating tissue dressing apparatus including one or more predetermined gases included in the reservoir thereof prior to use.

Applicant respectfully submits that the claimed invention relates to a new and simplified apparatus for supplying (for example) a therapeutic gas(es) to tissue and respectfully submits that the claimed apparatus is not in any way related to gas-generating bandage systems that were cited as prior art in the Action, and/or as disclosed in the specification of the subject application (see page 5). The known gas-generating systems employ gas-generating means for producing oxygen at the time of use to supply a wound using chemical or electrochemical means (see specification, page 5; U.S. patent nos. 5,855,570, 5,878,022, 5,788,682, and 6,000,403). In fact, Applicant had already distinguished the claimed invention from Ladin in this way in this section of the specification.

The currently claimed embodiments of the present invention provide a tissue dressing apparatus in which a therapeutic gas (for example), at concentration levels greater than atmospheric, is already contained in the device prior to use and thus need not be generated at the time of use. Thus, when using the claimed invention for the treatment of burn wounds (for example), oxygen included in the reservoir of the tissue dressing at concentrations greater than atmospheric, establishes a wound environment with continuous exposure to such an oxygen level improving wound recovery; chemical or electrochemical generation of the gas is not required.

Moreover, the claimed embodiments of the invention do not require a tethered source of a therapeutic gas as in topical oxygen chambers known in the art (see U.S. patent nos.

5,154,697, 4,328,799, 5,478,310 and the like). The claimed invention allows for enormous cost savings, simplicity of manufacture and ease of use.

Since none of the prior art cited in the outstanding Office Action addresses the deficiencies of Ladin, claims 58, 100, 101, 104 and 113 are patentable over the cited prior art for at least the above-noted reasons. Since a review of the prior art of record did not turn up any disclosure, teaching or suggestion, to address the deficiencies of Ladin, these claims are also believed patentable over the prior art of record. The remainder of the claims depend from one or another of the distinguished independent claims and are thus patentable for the same reasons. Accordingly, Applicant respectfully requests withdrawal of the prior art rejections.

Applicant also notes particular additional aspects of independent claims 58, 100, 101 and 113, as well as the additional features recited in the dependent claims, are patentable in their own right. Thus, in addition to Applicant's arguments given above, Applicant also requests that the Examiner carefully review each of the claims to consider such additional aspects should the Examiner deem the above-noted arguments unpersuasive.

To that end, if the Examiner, after review of all the claims is still of the opinion that the claimed invention is still not patentable over the prior art, **Applicant respectfully requests that the Examiner contact Applicant's below named representative to discuss such issues so that the issues may be resolved and the application allowed.**

CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that all issues raised in the October 31, 2005 Office Action have been addressed and requests favorable reconsideration of the subject application. Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. **50-0311** (Reference No. 27542-501 UTIL).

If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at telephone number (212) 692-6803. All correspondence should be directed to our New York office at the below listed address.

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Respectfully submitted,



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